

Notice of Allowability

Application No.

09/807,757

Examiner

Daniel M Sullivan

Applicant(s)

OWENS ET AL.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Paper filed 14 June 2004.
2. ☒ The allowed claim(s) is/are 2,22,31-36,41 and 43-48.
3. ☒ The drawings filed on 17 April 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Matthew Hinsch on 8 July 2004.

The application has been amended as follows:

In the claims

Claims 22 and 36 have been amended to read as follows:

22. (Currently amended) An isolated polynucleotide comprising a smooth muscle (SM) α -A promoter/enhancer in operable association with a heterologous polynucleotide, wherein the promoter/enhancer comprises sufficient sequence from the first intron of the SM α -A gene to confer smooth muscle cell-specific expression *in vivo* and wherein the promoter/enhancer comprises a nucleic acid that hybridizes to the complement of SEQ ID NO:1 when DNA comprising the complement of SEQ ID NO:1 is hybridized in 0.5 M NaHPO₄, 7% sodium dodecyl sulfate (SDS), 1mM EDTA at 65° C, and washed in 0.1xSSC/0.1% SDS at 68° C.

36. (Currently amended) An isolated genetically-engineered host cell comprising a polynucleotide comprising a SM α -A promoter/enhancer in operable association with a

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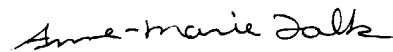
heterologous polynucleotide, wherein the promoter/enhancer comprises sufficient sequence from the first intron of the SM α -A gene to confer smooth muscle cell-specific expression *in vivo* and wherein the promoter/enhancer comprises a nucleic acid that hybridizes to the complement of SEQ ID NO:1 when DNA comprising the complement of SEQ m NO:1 is hybridized in 0.5 M NaHPO₄, 7% sodium dodecyl sulfate (SDS), 1mM EDTA at 65° C, and washed in 0.1xSSC/0.1% SDS at 68° C.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS


ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER